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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,194	12/03/2003	Robert B. Odell	P-4173C1C1	6906

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	**PAPER NUMBER**
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,194	ODELL ET AL.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/3/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner as to what constitutes a "substantially lower pressure", therefore rendering the independent claim and all of its dependent claims indefinite. It is also unclear to the Examiner as to what constitutes a "conventional syringe", therefore rendering the independent claims and all of its dependent claims indefinite. There are many types of syringes that can be considered "conventional" and would all produce a different injection pressure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howe (5,242,405). Howe discloses a syringe (20) comprising a syringe barrel (21) having an elongated body and chamber, an open proximal end, a distal end (33) and a frusto-conically shaped tip (34) extending from the distal end having a tip passageway therethrough in fluid communication with the chamber, a rubber stopper (39) in fluid-tight engagement inside the barrel, an elongated plunger rod (40) defining a longitudinal axis and extending proximally from the stopper through the open end, and a flange (not numbered) at the proximal end, a tip cap (44) for sealing the passageway, and a flush solution (43) in the chamber, the inside diameter of the of the chamber designed to produce a low pressure, wherein the chamber contains no more than 3.5 ml of solution, and the solution can be saline or heparin lock, wherein the syringe is packaged in a sterile package as is well-known in the art, and the barrel includes measuring indicia (35a).

Howe does not disclose that the chamber has a diameter of 13.5mm and a length of 57 mm but these dimensions are deemed to be matters of design choice and are not given much patentable weight. The Examiner points to the Applicant's admission in paragraph [0027] on page 6 of the specification, in which the Applicant discloses that a wide variety of dimensions could be used and the recited dimensions are only the preferred embodiment. Therefore, it would have been prima facie obvious to one of ordinary skill in the art to modify Howe with the dimensions recited in claims 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art Howe.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talonn et al. (5,395,339). Talonn discloses a syringe (150) comprising a syringe barrel (16) having an elongated body and chamber, an open proximal end, a distal end and a frusto-conically shaped tip (26) extending from the distal end having a tip passageway therethrough in fluid communication with the chamber, a rubber stopper (38) in fluid-tight engagement inside the barrel, an elongated plunger rod (154) defining a longitudinal axis and extending proximally from the stopper through the open end, and a flange (156) at the proximal end, a tip cap (26) for sealing the passageway, and a flush solution in the chamber, the inside diameter of the of the chamber designed to produce a low pressure, wherein the chamber contains no more than 3.5 ml of solution, and the solution can be saline or heparin lock, wherein the syringe is packaged in a sterile package as is well-known in the art, and the barrel includes measuring indicia.

Talonn does not disclose that the chamber has a diameter of 13.5mm and a length of 57 mm but these dimensions are deemed to be matters of design choice and are not given much patentable weight. The Examiner points to the Applicant's admission in paragraph [0027] on page 6 of the specification, in which the Applicant discloses that a wide variety of dimensions could be used and the recited dimensions are only the preferred embodiment. Therefore, it would have been prima facie obvious to one of ordinary skill in the art to modify Talonn with the dimensions recited in claims 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art Talonn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,361,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite the same structural features as the patented claims except for the obvious feature of the flange sized to contact the proximal end of the barrel. This limitation is well known in the art and would not be considered a patentable difference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Theodore J. Stigell

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